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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,367	10/30/2001	Barbara A. Brewitt	20371.0004c4	3277

7590 08/24/2004

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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,367	BREWITT, BARBARA A.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/30/01; 01/28/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is response to Applicant's election of species in claim 1. Election was made without traverse in the response filed 4/29/04. Further, Applicant traverses the species election requirement of claim 2. The traversal is on the ground(s) that under 37 C.F.R. 1.141, more than one species of an invention, not exceeding a reasonable number, may be specifically claimed in different claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim. The Office agrees with the argument. Therefore, claim 1 (as amended) and 2-20 will be examined. The species election requirement is deemed proper and made FINAL. Claims 1-20 are pending.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

3. The information disclosure statement, filed 10/30/2001 and 01/28/2002 have several duplicate references sited. Duplicate references have been identified as such.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 -18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claims 13, 16, 17 and 18 recites the limitation "C, X, and M" in the claims. The specification fails to define the terms so as to set forth the meets and bounds of the invention. In order to maintain a consistent claim language throughout the claims, the use of molar amounts as has been used in the original claim 1, is suggested.

3b. Claim 14 is indefinite because the meets and bounds of "a homeopathic potency" are not clear.

3c. Claims 15-18 are indefinite, improper and incorrect compositions claims, because they are drawn to more than one composition in a single composition claim. If the compositions are used separately, they would have to be claimed separately. If the compositions are added together to form a single final composition, the final concentration of the composition, as a single entity, may be claimed. For guidance, see the claims in the applicants' U. S. Patent No. 5, 629, 286 wherein two biologically active proteins together form one homeopathic composition.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the topical application of recombinant growth hormone (GH)

containing gel on the skin under the eye, does not reasonably provide enablement for the administration of compositions containing insulin-like growth factor-1 (IGF-1) to the throat, lungs, airways, nasal passages, eyes and skin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification as filed is insufficient to enable one skilled in the art to practice the claimed invention without an undue amount of experimentation. Although, growth hormone and IGF-1 are both growth factors, they are functionally different. For example, Applicant has shown that the application of GH containing gel on skin will remove the wrinkle under the eye (example 1). However, it is unclear if IGF-1 containing gel can be applied in the same manner. Further, Applicant has not provided any guidance with respect to the administration of IGF-1 to the throat, lungs, airways, nasal passages and

eyes. Since there is no guidance provided with respect to the various ailments affecting throat, lung, airways, nasal passages and eye, one of ordinary skill in the art would not be able to make and use the instant invention. Since the therapeutic effect of the compound identified (IGF-1) can be model-dependent, the disclosed studies (example 1) is not adequate to represent the various diseases affecting throat, lung, airways, nasal passages and eye. In addition, there is no guidance provided in choosing the effective amount for administering to the subjects to treat conditions affecting throat, lung, airways, nasal passages and eye. Applicant recites a broad, arbitrary, range with no evidence of the amount potency necessary to achieve the desired effect in any given tissue/organ. Since applicant has not provided any working examples of the efficacy IGF-1 in treating already established disease subjects or applicable model, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claim 5 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention to treat conditions affecting throat, lung, airways, nasal passages and eye using the IGF-1.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 1, 4-10, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Antoniades et al. (U. S. Patent No. 5, 035, 887).

Antoniades et al. describe using IGF-1 alone and in combination with PDGF for wound healing (column 5, lines 5-15). It teaches that 500ng -1μg of purified IGF-1 alone or in combination with PDGF was used for wound treatment. Thus, meeting the limitations of claims 1 and 14 because homeopathic preparation or potency has no patentable weight. Further the recitation of oral administration, administration to the throat or lungs, for delivery transdermally, for delivery in a cosmetic or personal care product and for vaginal or anal delivery, for topical application etc. in the claims is interpreted as an intended use and bears no accorded patentable weight. In addition, the Office is equating 500ng -1μg of IGF-1 to be less than $1x10^{-6}$ M based on a molecular weight of 7.6 KD. Antoniades et al teaches the application of compositions in a biocompatible gel to the skin (column 5, line 7-10). Thus, meeting the limitations of claims 9. It also describes 90% or greater purified IGF-1 and PDGF (column 2, lines 51-55). This meets the limitation of claim 10. Therefore, Antoniades et al. (U. S. Patent No. 5, 035, 887) anticipates claims 1, 4-10, 12 and 14.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6a. Claims 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Vithoulkas et al. (1981).

The teaching of Antoniades et al. has been described above in paragraph 5a. However, it does not describe compositions of various homeopathic potencies. Vithoulkas et al. describe the various potencies in detail. They describe the preparation (page 161) and the nomenclature (164) used in homeopathy.

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time invention was made to use the IGF-1 protein in low doses as taught by Antoniades et al. in the homeopathic potencies described by of Vithoulkas et al. The motivation to use IGF-1 is provided by Antoniades et al. in that they demonstrate that this facilitates the wound healing process (column 5, lines 30-45). There is a reasonable expectation of success because Vithoulkas et al. have described the derivation of potencies for therapeutic purposes. Although, the references does not recite any specific composition for administration, one of skilled in the art can use different compositions to optimize the therapeutic effect. Therefore, the claims 13 and 15-18 are obvious over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Vithoulkas et al. (1981).

6b. Claims 2, 3, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797).

6b. Claims 2, 3, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797).

The teaching of Antoniades et al. has been described above in paragraph 5a. However, it does not describe recombinant IGF-1 and a compositions comprising GH. Clark et al. describe the administration of IGF-1 and GH for the treatment of obesity (see claim 1). In addition, it teaches that these are recombinant human proteins that are purified (column 8, lines 11-65 and example III). Clark et al. also describe that the composition is in liquid form and it contains an amino acid (column 16, lines 14-23: column 15, lines 60-67).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time invention was made to use the purified recombinant IGF-1 and GH containing an amino acid in a liquid form as described by Clark et al. in low doses equivalent to homeopathic potencies as taught by Antoniades et al. Cark et al. provide the motivation to use purified recombinant IGF-1 and GH composition in a liquid form containing an amino acid, to treat obesity (claim 1). There is a reasonable expectation of success because Clark et al. have used IGF-1 and GH combination for the treatment of obesity (example III). Therefore, the claims 2, 3, 11 and 20 are obvious over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Clark et al. (U. S. Patent No. 5, 597, 797).

6c. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Whitson-Fischman et al. (U. S. Patent No. 5, 162, 037).

The teaching of Antoniades et al. has been described above in paragraph 5a. However, it does not describe recombinant IGF-1 in a compositions comprising other homeopathics selected from arsenicum, aconite and hypericum etc. Whitson-Fischman et al. describe a homeopathic medicament for the treatment of broad-spectrum viral infection containing herb hypericum (column 17, lines 35-40).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time invention was made to use the IGF-1 protein in low doses as taught by Antoniades et al. in the homeopathic medicament described by of Whitson-Fischman et al containing herb hypericum. The motivation to use IGF-1 is provided by Antoniades et al. in that they demonstrate that this facilitates the wound healing process (column 5, lines 30-45). There is a reasonable expectation of success because Whitson-Fischman et al. have described the medicaments containing hypericum for treament of cancer (column 17, lines 35-40). Therefore, the claim 19 is obvious over Antoniades et al. (U. S. Patent No. 5, 035, 887) in view of Whitson-Fischman et al. (U. S. Patent No. 5, 162, 037).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7a. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,629,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the cited patent claims.

7b. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,239,105. Although the conflicting claims are not identical, they are not patentably distinct from

each other because the subject matter claimed in the instant application is fully disclosed in the cited patent claims (see claims 1, 6 and 13).

8. No claims are allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 07/04

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